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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,595	02/02/1999	JORG REIMANN	9325-0008.30	8928

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/241,595

Applicant(s)

REIMANN ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,14-19,22-27 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,14-19,22-27 and 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/30/04 has been entered. Also, as requested, applicant's amendment received on 5/27/04 has been entered. Claims 3, 13, 20-21, and 28 have been canceled. Claims 1, 4-11, 14-19, 22-27, and 29-35 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code not included in this action can be found in the previous office action.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 3-11, and 13-35 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of applicant's amendment to the claims to recite that the composition is administered "in a manner so as to elicit a CTL response".

The rejection of claims 1, 3-11, 13-26, and 31-35 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn in view of applicant's amendment to the claims

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deleting the language which stated that the biologically active molecule is not covalently modified.

The rejection of claims 28 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's cancellation or amendments to the claims.

Applicant's amendments have resulted in the following new grounds of rejection under 35 U.S.C. 112, second paragraph.

Claims 27, and 29-30 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 as amended now recites the limitation of incubating the particle "at between about 35°C and about 60°C". The phrase "at between about" is confusing in that the metes and bounds of the range cannot be determined.

Claim Rejections - 35 USC § 102

The rejection of claims 27, and 29-30 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,039,522 (8/13/91), hereafter referred to as Neurath, is withdrawn in view of

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applicant's amendments to the claims which added the limitation that the particle and biologically active molecule are incubated together at between about 35°C and about 60 °C.

Applicant's amendments to the claims have resulted in the following new grounds of rejection under 35 U.S.C. 102(b).

Claims 1, 4-11, 14-19, 22-26, and 31-35 are newly rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,039,522 (8/13/91), hereafter referred to as Neurath et al., as evidenced by Schirmbeck et al. (1996) Intervirology, Vol. 39 (1), 111-119.

Neurath teaches that it is possible to add any peptide with a hydrophobic tail to HBsAg particles to produce an immunogen useful for generating immune responses against viral proteins or peptides (Neurath et al., column 3, lines 39-51, columns 11-12, claims 1-17). Neurath further teaches that the peptide can be a naturally occurring or synthetic peptide derived from HIV or hepatitis B (Neurath, column 3, lines 46-62). Neurath also teaches the preparation of HBsAg particles which contain myristolated hepatitis B preS antigen by incubating myristolated preS protein with HBsAg in an aqueous media (Neurath, column 10, lines 13-48). Please note that while the peptide is covalently bonded to the myristal andehyde, Neurath et al. clearly indicates that the absorption of myristilated peptide to HBsAg particle is a **non-covalent** interaction (Neurath et al., column 11, lines 28-34). Furthermore, the absorption of the myristilated peptide into the HBsAg particle results in the presence of the peptide on the surface of the HBsAg particle as evidenced by the recognition of the complexed

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HBsAg with antibodies against the myristilated peptide. In addition, Neurath teaches the immunization of rabbits with the preS containing HBsAg particles resulting in the generation of anti-HBV antibodies (Neurath, column 11, lines 9-51). It is also noted that antigens are inherently considered immunostimulatory molecules as their expression results in the generation of immune responses.

In regards to the claim limitation regarding the generation of CTL responses, while Neurath et al. did not test to see whether the administration of the HBsAg particles generated a CTL response in addition to the observed antibody responses, the method taught by Neurath et al. would naturally result in the generation of CTL responses because HBsAg particles are inherently capable of stimulating cytotoxic T cells. See Schirmbeck et al. for evidence that the administration of HBsAg particles without adjuvants efficiently primes class I-restricted CTL responses in addition to generating antibody responses (Schrimbeck et al., page 111, abstract, and page 115, Table 4). Thus, the ability to prime CTL is an inherent property of HBsAg. The applicant is further reminded that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. In re Woodruff, 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990); In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and Ex Parte Novitski, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993). In the instant case, Neurath et al. teaches a method using the exact same method steps and compositions as applicant's claimed methods. Therefore, Neurath et al. anticipates the instant invention as claimed.

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No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal line extending from the end of the signature.